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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,151	08/08/2003	Ake Larsson	P03,0282	6077

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EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/638,151	Applicant(s) LARSSON, AKE	
	Examiner Deborah Malamud	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/03, 1/9/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because of minor informalities. See attached PTO-948. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: some of the titles used in the specification are misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as obvious over Zarychta (U.S. 6,411,843) in view of Lurie et al (U.S. 6,234,985). Regarding claims 1 and 4-5, Zarychta discloses (column 2, lines 32-35) "producing a model EMG signal from a measured EMG signal that includes a patient's EMG signal and an ECG signal." To measure this EMG signal (column 6, lines 20-26) "electrodes (12a and 12b) are preferably positioned in esophagus with one electrode (12a) placed very close to diaphragm and the other electrode (12b) placed away from the diaphragm. Electrodes are connected to an EMG signal processing system (14) disposed outside patient." The examiner considers this to teach an esophageal electrode and a signal analyzer connected to the esophageal electrode. Zarychta further discloses (column 7, lines 32-35) "the EMG signals can also be used to control the application of electrical stimulation to the upper airway muscles and/or nerves to treat obstructive sleep apnea." Zarychta fails to teach stimulating the phrenic nerve. Lurie however discloses (column 8, lines 57-61) "signals from module (34) are also transferred to a stimulation control and pulse sequence generator module (36) which is responsible for producing electrical signals employed by electrodes (22, see FIG. 3)." The examiner considers this to be a pulse generator. Lurie further discloses (column 2, lines 34-41) "the diaphragm is stimulated

to contract by supplying electrical current or a magnetic field to various nerves or muscle bundles.” In one preferred aspect, “electrical current or a magnetic field is provided to the phrenic nerve.” The examiner considers this to be an electrode arrangement connected to the pulse generator for stimulating the phrenic nerve. Zarychta and Lurie both teach stimulation of the thoracic region in order to treat a cardiorespiratory condition. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Zarychta’s esophageal electrode with Lurie’s phrenic nerve stimulating electrodes in order to treat a respiratory condition by causing the diaphragm to contract.

Regarding claims 2 and 3, Zarychta discloses (column 2, lines 27-30) “in the case of a diaphragm EMG signal, the model diaphragm EMG signal can be utilized, for example, to synchronize the operation of a ventilator and the breathing cycles of a patient.” Zarychta further discloses (column 7, lines 10-20) “EMG signal processing system (14) receives measured EMG signal (17) from electrodes (12a, 12b and/or 16a, 16b), generates, and supplies to ventilator (18) an amplified model diaphragm EMG signal (19) that corresponds to the diaphragm EMG signal received at diaphragm (10). In a preferred embodiment of the present invention, the amplified model diaphragm EMG signal is used to synchronize the operation of ventilator with the patient’s breathing cycle so that the application of an inspiratory pressure or flow by the ventilator is synchronized with the inspiratory effort of the patient, and likewise, the patient’s expiration is synchronized to the expiratory cycle of the ventilator.” The examiner considers this ventilator to be a monitoring unit adapted to interact with the living subject

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for monitoring breathing and generates a monitoring unit output supplied to the regulating unit.

Regarding claim 6, Lurie discloses (column 11, lines 41-42) "electrical lead (66) is provided to supply electrical current to electrode (62)." Lurie discloses only one electrode lead, but it would have been obvious to one of ordinary skill in the art at the time of the invention to provide multiple leads, since it has been found that multiplication of a device's working elements requires only ordinary skill in the art.

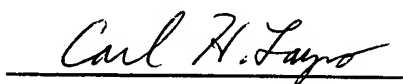
Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CARL LAYNO
PRIMARY EXAMINER

for Robert E. Pezzuto, SPE



Deborah L. Malamud
Patent Examiner
Art Unit 3766